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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/683,003

11/07/2001

Shiguang Yu

6601-00-HL

5003

23909

7590

04/03/2008

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EXAMINER

CHOI, FRANK I

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

04/03/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/683,003	<b>Applicant(s)</b> YU ET AL.	
	<b>Examiner</b> FRANK I. CHOI	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2 and 8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2 and 8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20080317</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/17/2008 has been entered.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no disclosure of hair modification. The Specification only discloses hair removal, i.e. shaving or clipping. Hair modification encompasses more than just shaving or clipping. The Applicant has not shown that any modification to hair was contemplated by the inventors at the time the application was filed.

Claims 2, 8 are rejected under 35 U.S.C. 112, first paragraph, because the specification is not enabling for a method of increasing hair growth in a dog or cat fed a properly nutritious diet and has had direct hair modification.

*The nature of the invention:*

The claims are directed to increasing the rate of hair growth in dog or cat who have had hair modification and which receive a properly nutritious diet with about 0.5 to about 4.5 mg/kg of the diet on a dry matter basis.

*The state of the prior art and the predictability or lack thereof in the art:*

The prior art of record discloses that dietary supplementation of selenium in can increase wool production in sheep, that selenium toxicity in dogs, cats and sheep can result in hair loss or alopecia and that selenium should be provided in or reduced to levels which do not result in toxicity. The prior art of record also discloses that hypothyroidism can result in poor hair growth or alopecia and that selenium supplementation is effective in treating hypothyroidism. As such, predictability in the art is low with respect to treatment of poor hair growth or alopecia other than in wool production of sheep, selenium toxicity or hypothyroidism resulting from selenium deficiency.

*The amount of direction or guidance present and the presence or absence of working examples:*

The Specification provides one example in which hair is shaved from different areas on dogs and the rate of hair growth is measured over time in relation to the amount of selenium (provided as selenomethionine) provided in a diet which is nutritionally balanced and complete for an adult dog except for selenium (Specification, paragraphs 0010-0015). As such, the hair and hair follicle is still present. Alopecia, on the other hand, is the absence or loss of hair. See Stedman's Medical Dictionary (27<sup>th</sup> ed. 2000) (printed from <http://www.thomsonhc.com/pdrel/librarian/PFDefaultActionId/pdrcommon.Stedmans> on 11/2/2006). Since the example does not show that selenium administration result in new hair growth, the example does not provide

evidence that administration of selenium will treat alopecia. The test showed hair growth of cut hair at each amount tested although at certain amounts (0.034, 0.085, 5.045 mg/kg dietary Se) there was decreased hair growth at week 11 and week 22 compared to other amounts (0.123, 0.527, 1.025 mg/kg dietary Se (Paragraph 0015, Table 1). In an article in which the inventors were the named authors, the article indicated that the daily hair growth for beagle dogs is 0.34-0.40 mm (Yu et al., Page 150). This is higher than any of the daily hair growth rate data set forth in Table 1 of the Specification. As such, the only example provided actually provides evidence the claimed range is not effective to increase hair growth in all animals, especially dogs. There is no disclosure of hair modification. The Specification only discloses hair removal, i.e shaving or clipping.

*The breadth of the claims and the quantity of experimentation needed:*

The claims are broad in that they claim increasing hair growth in a cat or dog which receives a properly nutritious diet and was subject to direct hair modification. The evidence submitted and the prior art of record does not provide evidence that selenium would be effective in increasing hair growth in cats or dogs as claimed. The example in the Specification sets forth hair growth rates in beagles in amounts falling within the claimed range of selenium that are below the daily hair growth rate in beagles and the diet used was deficient in selenium and had to be supplemented with selenium. The prior art discloses or suggests providing amounts of dietary selenium in or reducing amounts of dietary selenium to levels which are not toxic as selenium toxicity can cause poor hair growth or alopecia. The prior art discloses that selenium supplementation can treat hypothyroidism and that hypothyroidism can cause poor hair growth or alopecia. However, the prior art does not disclose that dietary selenium at the levels claimed

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is generally effective in increasing hair growth in cats or dogs subject to direct hair modification, what ever the case, including clipping. As such, it appears that one of ordinary skill in the art would be required to do undue experimentation in order to determine that administration of selenium in a “properly nutritious diet” would be effective in increasing hair growth in cats or dogs due to direct hair modification.

The Examiner has duly considered the Applicant’s arguments but deems them unpersuasive for the reasons above and the further reasons below. The Applicant refers to several publications in support of the argument as to enablement. Said publications are not sufficient to overcome the rejection herein in that the evidence is not in affidavit or declaration form. “The reason for requiring evidence in declaration or affidavit form is to obtain the assurances that any statements or representations made are correct, as provided by 35 U.S.C. 25 and 18 U.S.C. 1001.” Permitting a publication to substitute for expert testimony would circumvent the guarantees built into the statute. *Ex parte Gray*, 10 USPQ2d 1922, 1928 (Bd. Pat. App. & Inter. 1989). As such, the Applicant has not shown that the dogs were fed a properly nutritious diet or that the supplementation of selenium resulted in the increase in the rate of hair growth in the dogs tested. Also, the Applicant is incorrect in that the beagles did not show signs of selenium deficiency. Poor hair growth and/or loss of hair is disclosed or suggested by the prior art as a sign of both selenium deficiency and selenium toxicity. In any case, the fact remains that as tested the growth rate of the hair of the beagles given selenium did not exceed the normal hair growth rate of beagles, as such, the test does not provide sufficient evidence that hair growth was increased in beagles much less in dogs and cats in general.

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*Conclusion*

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi  
Patent Examiner  
Technology Center 1600  
April 4, 2008

/Johann R. Richter/  
Supervisory Patent Examiner, Art Unit 1616